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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,512	05/05/2000	MICHAEL ANTHONY JOHNSON	2-00US	2004
23713	7590	05/17/2004	EXAMINER WINKLER, ULRIKE	
GREENLEE WINNER AND SULLIVAN P C 5370 MANHATTAN CIRCLE SUITE 201 BOULDER, CO 80303			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,512

Applicant(s)

JOHNSON ET AL.

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 27, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,25,26,28-32,39-42 and 44-62 is/are pending in the application.
- 4a) Of the above claim(s) 28-32, 45-50 and 52-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,25,26,39-42,44 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The Amendment filed February 27, 2004 in response to the Office Action of August 27, 2003 is acknowledged and has been entered. Claims 1, 2, 4, 25, 26, 28-32, 39-42, 44-62 are pending and claims 1, 2, 4, 25, 26, 39-42 and 44 are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 1, 2, 4, 25, 26, 28-32, 39-42, 44 and 51 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **maintained** for reasons of record.

Applicant's arguments and the second 37 C.F.R. 1.132 declaration of Jeffrey Hammond filed February 27, 2004, have been fully considered but they fail to persuade.

The second 37 C.F.R. 1.132 declaration of Jeffrey Hammond filed February 27, 2004, is insufficient to overcome the prior rejection, as the declaration is not commensurate in scope with the claims. The declaration indicates that only some of the PAV3 gene sequences were available at the time of filing the instant specification. The sequences available were those PAV3 sequences spanning map units 50-55, 55-65, 72-85 and those sequences specifically disclosed by applicant. The classification of the various PAV into the same genus *Mastadenoviridae* is not sufficient to provide any structural knowledge of the individual PAV other than the PAV3. The sequences provided in the specification are the promoter elements and the leader sequences. The major late promoter leader sequences and the tripartite leader sequence are used in the

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construction of the expression cassette for the insertion of a heterologous sequence into the PAV3. The declaration is insufficient to overcome the prior rejections, as the declaration is not commensurate in scope with the claims the declaration has not provided any information regarding the structure of any other PAV other than PAV3.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor in the specification is a partial structure in the form of the major late promoter and tripartite leader sequence. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus which reads on all porcine adenoviruses discovered and those yet to be discovered. Furthermore, at the time of filing there was no information in the art or in the specification regarding sequences of other PAV genomes, this information is necessary to insert heterologous genes into regions other than the E3 and *rhe* region of PAV3. In order for homologous recombination to take place the key requirement is the alignment of homologous sequences in two DNA molecules, in the is case these sequences will be present in the wild type virus and they will also need to be present in the shuttle vector providing the heterologous sequence of interest which is to be inserted into the porcine adenovirus. To create the appropriate shuttle vector requires structural knowledge f the region into which the heterologous sequence is to be inserted.

There is a requirement for structural knowledge regarding the insertion points in the porcine adenoviral vector, the instant invention does not provide a sufficient written description for insertion into regions other than the E3 [map units 81-84 of PAV3] or *rhe* [map units 97-99.5 of PAV3] right hand genome region or for the use of another promoter cassette. Therefore, the instant specification does not provide sufficient written description for the breadth of the claimed invention.

The rejection of claims 1, 2, 4, 25, 26, 28-32, 39-42, 44 and 51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is **maintained** for reasons of record.

Applicant's arguments and the second 37 C.F.R. 1.132 declaration of Jeffrey Hammond filed February 27, 2004, have been fully considered but they fail to persuade.

The second 37 C.F.R. 1.132 declaration of Jeffrey Hammond filed February 27, 2004, is insufficient to overcome the prior rejection, as the declaration is not commensurate in scope with the claims. The declaration indicates that only some of the PAV3 gene sequences were available at the time of filing the instant specification map units 50-55, 55-65, 72-85 and those sequences specifically disclosed by applicant. The classification of the various PAV into the same genus *Mastadenoviridae* is not sufficient to provide any structural knowledge of the individual PAV other than the PAV3. The sequences provided in the specification are the promoter elements and the leader sequences. The major late promoter leader sequences and the tripartite leader sequence are used in the construction of the expression cassette for the insertion of a

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heterologous sequence into the PAV3. The declaration is insufficient to overcome the prior rejections, as the declaration is not commensurate in scope with the claims the declaration has not provided any information regarding the structure of any other PAV other than PAV3.

Applicants in their instant specification have provided the necessary structures in order to produce a major late promoter cassette of PAV-3, which they used for the homologues recombination in order to produce porcine adenoviral vector that has a heterologous gene sequence inserted. Neither the specification or the prior art have provide the requisite knowledge regarding the structure of other PAV genomes, this information would be required if applicants intend to insert heterologous genes into regions other than the PAV3 regions disclosed. In order for homologous recombination to take place the key requirement is the alignment of homologous sequences in two DNA molecules, in the is case these sequences will be present in the wild type virus and they will also need to be present in the shuttle vector providing the heterologous sequence of interest which is to be inserted into the porcine adenovirus. To create the appropriate shuttle vector requires structural knowledge of the region into which the heterologous sequence is to be inserted.

Thus, the lack of working examples for any other insertion site in any other PAV, lack of guidance regarding the structure of the porcine adenoviral genome in the specification and the prior art, and the great breadth of the claims greatly reduces the probability that one of skill in the art would successfully obtain the claimed invention without undue experimentation.

Conclusion

No claims are allowed.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/14/04